MAY 0 6 2002

K012680

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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
11400 73rd Avenue North
Minneapolis, MN 55369
Ph: 888-856-4870
Fax: 763-488-3350

Date Prepared: August 8, 2001

Trade Name: SterilMed Reprocessed ERCP Cannulas

Classification Name and Number: Biliary Catheter, Class II,
21 CFR 876.5010

Product Code: FGE

Predicate Device(s): SterilMed's reprocessed ERCP Cannulas are substantially equivalent to:

- Boston Scientific's Microvasive FluoroTip ERCP Cannula (K833417)
- Boston Scientific's Microvasive Endoscopic Biliary Catheter (K946358)
- The counterpart devices from the original manufacturers

Device Description: SterilMed's reprocessed ERCP cannulas consist of a firm, low friction shaft (lumen) with an injection side port and stylet adapter at the proximal end, and may be placed in the biliary tree with or without the assistance of a guidewire. The side port allows for the injection of contrast media to facilitate cholangiography. The stylet adapter stiffens the cannula during scope passage The cannulas have a radiopaque distal tip to aid in catheter visualization during fluoroscopy/cholangiography. These devices can be curved or straight and are available in varying lengths and diameters.

Intended Use: Reprocessed ERCP cannulas are intended to aid in diagnostic procedures for suspected biliary tract obstruction (such as strictures or stones). ERCP cannulas are used

during endoscopic procedures to provide a pathway to the bile duct and provide a port to inject the biliary tree with contrast media to identify blockages, and for cholangiopancreatography.

Functional and Safety Testing:

Representative samples of reprocessed ERCP Cannulas underwent design testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:

SterilMed's reprocessed ERCP Cannulas are substantially equivalent to:

- Boston Scientific's Microvasive FluoroTip ERCP Cannula (K833417)
- Boston Scientific's Microvasive Endoscopic Biliary Catheter (K946358)
- The counterpart devices from the original manufacturers.

This conclusion is based upon the fact that these devices' are essentially identical to their predicate devices in terms of functional design, indications for use, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2002

Mr. Patrick Fleischhacker
V.P. Regulatory and Quality Control
SterilMed, Inc.
11400 73rd Avenue North
MAPLE GROVE MN 55369

Re: K012680
Trade/Device Name: See enclosure
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: April 12, 2002
Received: April 16, 2002

Dear Mr. Fleischhacker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012686

Indications for Use Page

Device Name: Reprocessed ERCP Cannulas

Indications for Use:

Reprocessed ERCP cannulas are intended to aid in diagnostic procedures for suspected biliary tract obstruction (such as strictures or stones). ERCP cannulas are used during endoscopic procedures to provide a pathway to the bile duct and provide a port to inject the biliary tree with contrast media to identify blockages, and for cholangiopancreatography.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012680